EXHIBIT F

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IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF WEST VIRGINIA
CHARLESTON DIVISION

IN RE: ETHICON INC. PELVIC REPAIR SYSTEM PRODUCTS LIABILITY LITIGATION	**MDL No. 2327**
	2:12-cv-01318
THIS DOCUMENT RELATES TO:	**HON. JOSEPH R. GOODWIN**
Deborah Mattingly et al., v Ethicon Inc., et al.,	

RULE 26 EXPERT REPORT OF KONSTANTIN WALMSLEY, MD

My name is Konstantin Walmsley. I have been retained by the Bern Ripka Law Firm to give medical opinions related to Deborah Mattingly. I am being compensated at the rate of $500 dollars/hour. My curriculum vitae is attached to this report as **Ex. A**. All opinions set forth in this report are based upon my personal knowledge, as well as my review of the pertinent medical records, my education, training, skill, experience as a physician, and review of the pertinent medical literature. All of my opinions are based upon a reasonable degree of medical and scientific certainty. My reliance list is attached as **Ex. B**.

I am a licensed physician in the State of New Jersey and a board certified urologist. I am familiar with the evaluation and treatment of stress urinary incontinence and prolapse. I have implanted transvaginal mesh and am familiar with the properties of these devices and proper implantation technique for these devices. Additionally, I am familiar with proper patient selection for these devices. I have explanted and performed other revision procedures on transvaginal mesh.

Additionally, in light of my training, knowledge, experience and qualifications as set forth above and in the attached C.V., I am familiar with the

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medical complications that are generally associated with mesh repair surgery, and I am experienced in the recognition, diagnosis and treatment of patients suffering from complications caused by pelvic repair mesh implants including, not limited to, the TVT retropubic and other mid urethral slings.

Medical records reviewed include:

- Dr. Basim Kahleifeh
- Springview Urology
- Spring View Hospital
- Taylor Regional Hospital

Clinical History

- On March 27, 2009, Mrs. Mattingly underwent TVT insertion, anterior colporraphy, and posterior repair by Dr. James Angel. Pre-operative H and P indicated a history of a partial hysterectomy in 2002, history of a herniated disc, and degenerative disc disease. The operative dictation memorializes tension-free placement of the TVT device via retropubic access. Interestingly, there is no description of the anterior colporraphy within the body of Dr. Angel's operative dictation.

- On May 11, 2011, Dr. Eugene Shively performed an open sacral vaginopexy using intraperitoneal mesh on Mrs. Mattingly. Preoperative H and P indicated that Mrs. Mattingly had urodynamics demonstrating no SUI and a normal cystoscopy. Her pelvic exam revealed a grade III cystocele and a rectocele.

- On October 15, 2014, Mrs. Mattingly saw Dr. Kriegler with complaints of recurrent UTI symptoms, mild SUI, urgency, and lower back/suprapubic pain. She had symptoms of urgency, vaginal itching/burning, and dyspareunia. On physical exam, she was found to have suprapubic tenderness. Her post-void residual was 40 cc. Urine analysis was negative. Bactrim DS was prescribed.

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- On October 31, 2014, Mrs. Mattingly saw Dr. Kriegler with complaints of recurrent UTI symptoms, mild SUI, urgency, and lower back/suprapubic pain. She had symptoms of urgency, vaginal itching/burning, and dyspareunia. On physical exam, she was found to have a grade I cystocele, no mesh erosion, and a vaginal rash. Cystoscopy was normal and a Marshall test was negative. She was placed on antibiotic prophylaxis and advised to use vinegar douches.

- On June 9, 2015, Mrs. Mattingly saw Dr. Kriegler with complaints of recurrent UTI symptoms, hematuria, and lower back/suprapubic pain. She had gross total painful hematuria for 3 days that stopped spontaneously. She had symptoms of urgency, vaginal itching/burning, and dyspareunia. She was found to have a grade I cystocele, no mesh erosion, and a vaginal rash. Her post-void residual was 10 cc.

- On August 12, 2015, Mrs. Mattingly saw Dr. Kriegler with complaints of recurrent UTI symptoms, hematuria, and lower back/suprapubic pain. She had gross total painful hematuria for 3 days that stopped spontaneously. She had symptoms of urgency, vaginal itching/burning, dyspareunia. She was found to have a grade I cystocele, no mesh erosion, and a vaginal rash. Cystoscopy confirmed a grade I cystocele, and a normal bladder with superficial capillaries noted throughout.

- On January 19, 2016, Mrs. Mattingly, saw Dr. Kriegler with complaints of recurrent UTI symptoms. Urinalysis was normal and pelvic exam revealed no prolapse or mesh erosion. Post-void residual (PVR) was 85 cc. She was prescribed Tamsulosin and had a vaginal culture sent.

- On April 5, 2016, Mrs. Mattingly saw Dr. Kriegler with complaints of incomplete bladder emptying (having not tolerated Tamsulosin) and UTI symptoms (having had multiple UTIs in the last year). Physical exam revealed a grade I cystocele as well as a vulvar and vaginal rash. PVR was 44 cc. She was provided a presciption for Terazosin as well as for Fluconazole and Mycolog-II cream.

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- On May 23, 2016, Mrs. Mattingly saw Dr. Kriegler with continued complaints of incomplete bladder emptying and UTI symptoms, citing specific pain when urine "hit her vagina". Physical exam revealed a grade I cystocele as well as a vulvar and vaginal rash. She was prescribed Pyridium, A and D ointment, and Mycolog-II cream.

Methodology

My case specific opinions are based upon a differential diagnosis methodology. In determining the specific cause of an injury in the medical context it is necessary to "rule in" potential causes of the injury, and then by process of elimination, to "rule out" the least likely causes to arrive at the most likely cause.

General Opinion No. 1

Facilitating informed consent is an integral part of the practice of medicine. I agree with AMA 8.08 on informed consent. The patient's right of self-decision is particularly important when surgical intervention regarding a permanent medical device is being considered by the patient.

Before a surgeon can inform a patient on the risks/benefits/alternatives to any procedure, including the TVT, the surgeon must be informed on the risks/benefits/alternatives. I have read and relied on Instructions for Use (IFU) for medical devices when informing myself on the risks/benefits/alternatives to a given procedures – including mid-urethral slings. I incorporate the risks and complications referenced in the IFU into my risk-benefit conversation with the patient. I expect the risk and complication information as presented in the IFU to be accurate.

It is my opinion the IFU for the TVT in 2009 was not sufficient to enable informed consent from the patient. The TVT IFU provided:

ADVERSE REACTIONS

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- Punctures or lacerations of vessels, nerves, bladder or bowel may occur during needle passage and may require surgical repair.
- Transitory local irritation at the wound site and a transitory foreign body response may occur. This response could result in extrusion, erosion, fistula formation and inflammation.
- As with all foreign bodies, PROLENE mesh may potentiate an existing infection. The plastic sheath initially covering the PROLENE mesh is designed to minimize the risk of contamination.
- Over correction (i.e. too much tension) applied to the tape may cause temporary or permanent lower urinary tract obstruction.

ACTIONS

Animal studies show that implantation of PROLENE mesh elicits a minimal inflammatory reaction in tissues, which is transient and is followed by the deposition of a thin fibrous layer of tissue which can grow through the interstices of the mesh, thus incorporating the mesh into adjacent tissue. The material is not absorbed, nor is it subject to degradation or weakening by the action of tissue enzymes.

The words "transitory" and "transient" carry a specific medical meaning. Mosby's medical dictionary defines transient as "pertaining to a condition that is temporary." Using the word transient to describe the human body's foreign body response to the TVT mesh implies the response dissipates with time. In my experience, this does not accurately describe the human body's foreign body response to transvaginal placed mesh.

In my experience when dealing with synthetic mesh-induced foreign body response, the degree of inflammation and scarring around the mesh is intense and chronic. More often than not, when removing exposed mesh, I am unable to completely remove the entire mesh implant because of the intensity of inflammation and extensive scarring induced by mesh incorporation into the host tissues. Moreover, in all of my experiences removing mesh, residual scarring of the vagina, peri-vaginal, and those tissues adjacent to the mesh persists and is even more severe in the instances where residual pelvic mesh is left in the patient.

The TVT IFU does not mention: mesh contraction; dyspareunia; mesh shrinkage; scar plate formation; or the difficulty in removing mesh in the event of an

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adverse event. These events are all part of my informed consent conversation today. I have treated patients implanted with mid-urethral slings, including the TVT for these conditions. It is my opinion that a patient considering a mid-urethral sling cannot be properly consented without discussing these potential adverse events.

General Opinion No. 2

In 2009, alternative successful and safer sling procedures were available, including autologous fascial slings using rectus fascia sutured to the bladder neck and tied to itself over the rectus fascia. Mrs. Mattingly was unable to receive proper informed consent relating to this safer alternative because of the lack of information in the TVT IFU inherent to the risks of using synthetic mesh. As such, Dr. Angel was unable to warn Mrs. Mattingly of the subsequent complications she has suffered from.

Case Specific Opinion No. 1

Mrs. Mattingly's vaginal pain and dyspareunia started after her TVT sling insertion. Recognized causes of dyspareunia following synthetic sling surgery include: (1) erosion/extrusion; (2) mesh contraction; (3) paraurethral banding; (4) scarring with reduced elasticity; (5) infection and inflammation including but not limited to vestibulitis; (6) neuromuscular injury; (7) lichen sclerosis; (8) vaginal tissue atrophy; and (9) pelvic floor dysfunction.

Of interest, there is clear evidence that Mrs. Mattingly did not have dyspareunia prior to her TVT surgery. What is less clear is: 1) if it preceded Dr. Shivley's surgery or 2) to what degree her other surgical procedures might have contributed to her pain and dyspareunia.

I am able to rule out erosion; paraurethral banding; lichen sclerosis; and vaginal tissue atrophy potential causes of Mrs. Mattingly's vaginal pain and dyspareunia because I have not seen these findings documented. Infection and inflammation are possible causes of Mrs. Mattingly's dyspareunia although there are insatnces in which she has dyspareunia in the absence of infectious or inflammatory processes. I am not able to rule in neuromuscular injury or pelvic floor dysfunction as a causative factor having not seen this in the medical records either. The one other plausible mesh-related cause for Mrs. Mattingly's pelvic pain and dyspareunia, vaginal scarring with reduced elasticity (in the area of the implant), is also not seen within the medical records.

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In summary, Mrs. Mattingly's dyspareunia has no clear etiology based on the current medical records I have reviewed. Within a reasonable degree of medical certainty, it began after her pelvic surgeries. To what extent it was caused specifically by the TVT is difficult to ascertain. The most effective way to corroborate, objectify and specify these issues would involve an independent medical examination that would shed more light as to the above questions.

Case Specific Opinion No. 2

Mrs. Mattingly has recurrent stress urinary incontinence, urinary urgency, and incomplete bladder emptying as a direct result of her TVT sling insertion. As part of the foreign body reaction to synthetic mesh the periurethral, perivesical, and vaginal tissues create dense fibrotic scar tissue which compromises the elasticity and compliance of these tissues. As such, when patients present with complications from synthetic mesh slings, they tend to develop a combination of voiding dysfunction, sometimes manifest as obstructive in nature, sometimes combined urinary incontinence that is often both stress incontinence in combination with urgency urinary incontinence. This relates to a combination of factors, one being the development of non-compliant "pipestem" urethral tissues that are unable to coapt and therefore hold urine; the second factor relates to a combination of (1) inflammation rendering the bladder muscle (or detrusor muscle) unstable, as well as (2) scarring of the bladder muscle adjacent to the synthetic mesh foreign body response, in which the bladder muscle's ability to contract is compromised because of scarring and fibrosis. Although Mrs. Mattingly, does not suffer from urgency urinary incontinence presently, she does have obstructive voiding symptoms including incomplete bladder emptying, urinary urgency, and recurrent SUI without findings of urethral hypermobility which is consistent with intrinsic sphincter deficiency seen in patients with non-compliant "pipestem" urethras.

Case Specific Opinion No. 3

Mrs. Mattingly's future prognosis as it relates to her pelvic pain, voiding dysfunction and dyspareunia is guarded. She continues to have severe pelvic pain, voiding dysfunction, and dyspareunia presently. Under the presumption that her dyspareunia and vaginal pain are caused by the TVT sling implanted in her by Dr. Angel, she will continue to suffer from these significant and life-altering complaints. Even if she were to have all of her mesh removed, the surgery require to execute this

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procedure is extensive, complicated, and almost exclusively performed in tertiary academic centers. Moreover, I anticipate that if heroic surgery were performed to remove all of her mesh that she would develop further scarring and fibrosis inherent to this procedure.

Regarding her SUI, although an autologous fascial sling or other procedures (not involving synthetic mesh) for incontinence might be considered, this would be more complicated at the current time because of the fact that she still has scar tissue and residual mesh present. Autologous fascial slings placed in the setting of scar tissue or mesh would have a lower success rate and a higher complication rate than if it were performed in the absence of scarring. For this reason, Mrs. Mattingly is not an ideal candidate for this type of surgery and is best treated with medical therapy in combination with lifestyle modifications and pelvic floor physiotherapy. Although these interventions should be somewhat helpful, they most certainly will not resolve the voiding dysfunction she currently suffers from.

I reserve the right to supplement and amend this opinion should additional factual information be forwarded to me that I did not have available at the time this opinion is submitted.

Dated this the 22nd day of July, 2016

Konstantin Walmsley, M.D.